EPMedSystems

ALERT® (Atrial Low Energy Reversion Therapy) Catheter

INSTRUCTIONS FOR USE

READ ALL WARNINGS, PRECAUTIONS AND INSTRUCTIONS PRIOR TO USE

The **ALERT®** Catheter has been designed to be used exclusively with the EPMedSystems **ALERT®** Companion™ and **ALERT®** Interface Cable.

FOR SINGLE USE ONLY
Destroy the catheter after use. Do not attempt to clean or resterilize a used catheter.

STERILE AND NON-PYROGENIC
The catheter is sterile and non-pyrogenic only if package is not damaged or open.

STORAGE AND USE
Store **ALERT®** Catheters at normal room temperature. Avoid prolonged exposure to direct light to protect the integrity of the latex balloon. Use product on a first-in, first-out basis prior to the expiration date on the label.

ELECTRICAL WARNING
The **ALERT®** Catheter, when inserted temporarily, is to be used for atrial defibrillation, intracardiac pacing / sensing and ECG recording only. Any other electrical use or inappropriate electrical connections may pose a serious risk of adverse health consequences or death.

WARNING
DO NOT USE THIS PRODUCT FOR ELECTRICAL ABLATION.

CONTRAINDICATION
This product utilizes a natural latex balloon and should be used with caution in patients with known sensitivity to latex proteins. Natural rubber latex is known to cause allergic reactions in certain sensitive patients.

CAUTION
Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

The ALERT® System is indicated for use in patients who are candidates for transvenous electrical cardioversion for the treatment of atrial fibrillation.

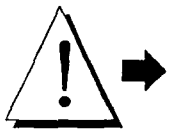
CONTRAINDICATIONS

The **ALERT®** System is contraindicated when any of the following conditions exist:

- The patient is not a suitable candidate for the placement and use of temporary intracardiac pacing leads,
- The patient is not a suitable candidate for internal atrial cardioversion,
- The patient has had a peripheral embolism or stroke within three months of the proposed date of cardioversion,
- The patient has a mechanical tricuspid or pulmonary valve (a prosthetic tissue valve is permissible),
- The patient has a heart condition for which defibrillation is contraindicated.
- The patient is allergic to latex. Natural rubber latex is known to cause allergic reactions in certain sensitive patients.

The following are Warnings and Precautions specific to the ALERT® catheter. Please refer to the ALERT® System Instruction Manual for Warnings and Precautions generally applicable to the ALERT® System.

WARNINGS



WARNING
Should external rescue defibrillation be required, the catheter must be disconnected from the Companion prior to the procedure.

Catheter Placement – Physicians must determine that the **ALERT®** Catheter is correctly positioned and that the **ALERT®** System adequately senses right ventricle electrical activity before attempting cardioversion. Refer to the INSTRUCTIONS FOR USE section of this document for guidance on proper catheter placement.

Thrombosis – The **ALERT®** System should not be used on patients with ongoing sepsis or a hypercoagulable state where the catheter could serve as a focal point for septic or bland thrombus formation.

Other Uses – The **ALERT®** System should be used only as indicated in the **ALERT®** System Instruction Manual . Any other use or inappropriate electrical connections could pose a serious risk of adverse health consequences or death. The **ALERT®** catheter should not be used for any type of **electrical ablation**. The **ALERT®** catheter should not be used with any **other defibrillator** except the **ALERT®** Companion™.

Balloon Inflation –

- Do not inflate the balloon beyond the maximum inflation capacity of 2.0cc. Exceeding this volume will not appreciably increase the diameter of the balloon and will increase the possibility of balloon rupture, which could result in a latex fragment embolism.
- During balloon inflation, as with any balloon-tipped catheter, use extreme care to minimize the possibility of pulmonary artery rupture.
- Never use any liquid (e.g., contrast media) for balloon inflation because the balloon may not deflate.
- Never inflate the balloon in ice water for testing.
- Always deflate the balloon prior to withdrawing the catheter.
- Use CO_2 for balloon inflation in any situation (i.e., intracardiac shunt) where a balloon rupture could result in a gas embolism entering the arterial circulation.

PRECAUTIONS

Patient Conditions – The user should consider the following patient conditions before using the **ALERT®** catheter:

- Profound electrolyte imbalance or digitalis toxicity should be corrected prior to attempting to cardiovert atrial fibrillation.
- Patients with long QT syndrome and rapid ventricular rate are at increased risk for ventricular fibrillation with cardioversion. In this situation the physician must be prepared to disconnect the **ALERT®** catheter from the Companion™ and apply external ventricular defibrillation.
- Patients with left bundle branch block are at increased risk for developing complete heart block with right ventricular catheterization. In this situation, the physician should have temporary pacing available.
- Post-open heart surgery patients were not included in the clinicial study and no information is available regarding the safety and efficacy of the **ALERT®** system in such patients.

Preparation –

CAUTION

The catheter has been sterilized using EtO. Do not attempt to sterilize the catheter by autoclave, gamma or ultraviolet radiation, or liquid sterilizing solutions. Do not use ultrasonic cleaners on the catheter.

- The **ALERT®** Catheter should be used only by or under the direct supervision of a physician thoroughly trained in the techniques of cardiac catheter placement, transvenous defibrillation, external and internal cardiac pacing, cardiopulmonary hemodynamics, intraventricular ECG recording, and electrophysiology.
- In the event of complications arising during the use of this device, the following items should be readily available: antiarrhythmic drugs, defibrillator, and respiratory assist equipment.

Stylets – The stylets packaged with the **ALERT®** Catheter are manufactured to match the length of each catheter. The use of stylets other than those packaged with the **ALERT®** Catheter could pose a risk of perforation if the stylet length is longer than the catheter. Therefore use only the stylets packaged with each catheter.

Handling, Insertion and Removal – If the body of the catheter is stretched or kinked, the internal wires running within the catheter body that connect to the electrodes may break or detach from the electrodes. When testing and preparing the catheter, avoid these actions:

- Stretching or pulling of the catheter body, such as forceful wiping
- Kinking the catheter

To avoid damage to the catheter and injury to the patient, follow these guidelines for insertion and removal:

- Use a vessel dilator or disposable sheath when performing a cutdown procedure.
- Never use forceps on the catheter.
- With femoral insertion, it is possible to transfix the femoral artery in some situations during percutaneous entry into the vein. Proper femoral vein puncture technique should be followed.
- Do not leave the catheter in the patient longer than 72 hours. The incidence of insertion site complications increases significantly with catheters which remain indwelling longer than this period.

Pressure Measurement – Accurate pressure measurements are possible only if the following measures are taken:

- Ensure that the pressure monitoring lumen within the catheter is patent by flushing the catheter with sterile saline before insertion.
- Eliminate air bubbles by flushing the catheter and the pressure-sensing device with sterile saline.
- Avoid leaks at the connections between the catheter and the pressure-sensing device.

CATHETER PRODUCT DESCRIPTION

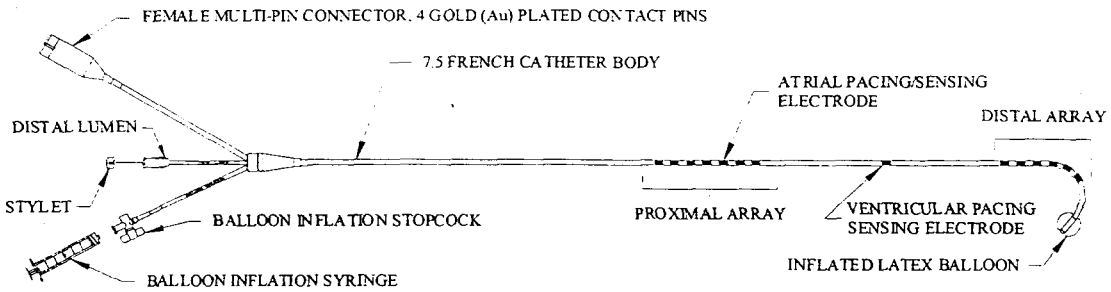


Figure 1: ALERT® (Atrial Low Energy Reversion Therapy) CATHETER

The ALERT® Catheter is a temporary transvenous flow-directed multi-purpose atrial defibrillation and pacing catheter. The ALERT® Catheter also provides a means to monitor intracardiac pressures, draw blood samples and infuse drugs. It has a usable length of 110 ± 5 cm. The catheter body consists of 7.5 French flexible radiopaque multi-lumen polymeric tubing.

Depth Markings: The catheter has 10 cm increments marked along its length. The insertion depth marks on the catheter illustrated above allow the physician to determine how much of the catheter has been inserted in the patient.

100	90	80	70	60	50	40	30	20	10
Proximal									Distal

Distal lumen: A large 0.028" distal lumen, centered in the tubing, is circumscribed by six smaller lumens. The distal lumen facilitates the passage of the catheter over a 0.021" diameter guidewire for insertion. This lumen also provides a means to draw blood samples, infuse drugs and measure blood pressures (RA, RV, CVP, PCWP, MPAP). The distal lumen terminates proximally with a female luer-lock hub extension and is marked "PA DISTAL".

Stylets: Two custom length (matched to catheter length), removable, user-formable stainless steel stylets (one straight and one with a pulmonary artery curve) are also supplied with the ALERT® Catheter and are placed in the distal lumen to aid in steering the distal tip of the catheter into the left pulmonary arch. Each stylet is Teflon® coated to simplify insertion and withdrawal. The stylet terminates proximally with a male luer-lock orbicular knob.

Other lumens: The remaining six smaller lumens are used to embody electrode conductor wires, a stiffening wire, and to provide balloon inflation. The **balloon inflation lumen** terminates distally with a natural latex balloon; fully inflated dimensions of the balloon are 8 mm x 13 mm. The proximal end of this lumen connects to a balloon inflation extension marked "BALLOON INFLATION," which includes a two-way stopcock with a female luer-lock hub.

The **stiffening wire lumen** contains a permanently-anchored, tapered stainless steel wire that terminates 10 cm proximal to the atrial (proximal) electrode array. The purpose of this wire is to provide control of the passive portion of the ALERT® Catheter from the vena cava proximally when inserted.

The **atrial pacing/sensing lumen** contains a conductor wire that connects distally to a 2 mm platinum electrode band (located within the proximal array approximately 30 cm from the distal tip) and terminates proximally with a gold-plated contact pin housed in a multi-pin connector.

The **ventricular pacing/sensing lumen** contains a conductor wire that connects distally to a 2 mm platinum electrode band (located approximately 18 cm from the distal tip) and also terminates proximally with a gold-plated contact pin housed in a multi-pin connector.

The **proximal (right atrial) defibrillation array lumen** contains a low resistance conductor wire that connects distally in series to six 5 mm platinum electrode bands spaced 5 mm apart (located approximately 28 cm from the most distal band to the distal tip) and terminates proximally with a gold-plated contact pin housed in a multi-pin connector.

The **distal (left pulmonary artery) defibrillation array lumen** contains a low resistance conductor wire that connects distally in series to six 5 mm platinum electrode bands spaced 4 mm apart (located approximately 4 cm from the most distal band to the distal tip) and terminates proximally with a gold-plated contact pin housed in a multi-pin connector.

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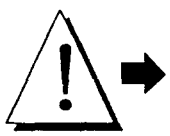
INSTRUCTIONS FOR USE

Storage and Handling – Store **ALERT®** Catheters at normal room temperature. Avoid prolonged exposure to direct light to protect the integrity of the latex balloon. Use product on a first-in, first-out basis prior to the expiration date on the label. It is a recommended practice to have on hand a duplicate of each sterilized item when introducing a catheter. Thus, if aseptic technique is compromised, the procedure can continue.

Single Use Only – **ALERT®** Catheters have been designed for one-time single patient use only. They are supplied sterile provided the package is undamaged and unopened.



CAUTION
The catheter has been sterilized using EtO. Do not attempt to sterilize the catheter by autoclave, gamma or ultraviolet radiation, or liquid sterilizing solutions. Do not use ultrasonic cleaners on the catheter.

Catheter Insertion and Positioning – The following instructions are provided as a general guide and are intended for informational purposes only; the physician may alter the catheter insertion techniques based on his/her standard clinical practice.

1. Prior to the procedure, the patient should be connected to an ECG recording system to permit monitoring for arrhythmias.
2. Remove the **ALERT®** Catheter from its packaging using sterile technique.
3. Inflate the balloon with air to the recommended volume and immerse the balloon in room temperature sterile water. If there is any evidence of air bubbles escaping around the balloon or the balloon will not remain inflated, do not use the catheter.
4. Flush the catheter extension marked "PA DISTAL" with bubble-free sterile saline solution.
5. Connect the distal extension to an appropriate hemodynamic pressure monitor via a transducer and fluid coupling extension line that have been flushed and are free of bubbles.
6. Facilitate catheter insertion into the desired vein by cutdown or percutaneous technique with a suitable size introducer sheath.
7. Insert the catheter into the vein and gently advance the catheter while continuously monitoring the ECG from body surface electrodes. If desired, monitor the pressure waveform. Fluoroscopy should always be used with a femoral approach.
8. If an internal jugular, subclavian, or antecubital approach is used, partially inflate the balloon upon reaching the superior vena cava. The monitored pressure waveform will begin to show respiratory variations when the catheter reaches this location. To confirm that the catheter is located within the thoracic cavity, have the patient cough and look for a large pressure change.
9. Upon reaching the right atrium, the balloon can be fully inflated. When the catheter is in position in the right atrium, an atrial waveform will be observed on the pressure monitor.
10. Gently advance the catheter into the right ventricle while monitoring the ECG for signs of ventricular irritability. When the catheter is positioned within the right ventricle, a ventricular pressure waveform will be observed on the pressure waveform monitor. Avoid entering the ventricle with the balloon deflated, as this will cause frequent premature ventricular contractions.
11. With the balloon inflated, advance the catheter by floating it into the pulmonary artery. If difficulty is encountered placing the catheter into its ultimate position within the left pulmonary arch in a balloon wedge position, disconnect the fluid coupling line from the distal lumen extension and cautiously insert and advance the curved stylet.
12. With the stylet fully inserted, twist the stylet to move the catheter into position. Do not advance or rotate the catheter if resistance is met.
13. If the catheter is difficult to position by means of the stylet, substitute a flexible 0.021" guidewire with a soft J-tip. Position the catheter in the right ventricular outflow tract and advance the guidewire into the left pulmonary artery. Advance the catheter over the wire to its final position. Proper placement of the catheter is obtained when the proximal array is positioned in the right atrium, the ventricular electrode is positioned in the right ventricle and the distal array is positioned in the left pulmonary artery.
14. If right ventricular capture is obtained and the sensing signal in the right ventricle is acceptable, then with the balloon deflated in the pulmonary artery, defibrillation may be performed. If difficulty is encountered obtaining right ventricular capture and sensing, the balloon may be inflated in a wedge position and the catheter advanced distally to move the right ventricular electrode deeper into the ventricular apex until an acceptable sensing signal is obtained. **Defibrillation may be performed only once an acceptable sensing signal is obtained.** Do not advance the catheter if this action meets with resistance. Do not leave the balloon inflated for an extended period of time.
15. Refer to the **ALERT®** System Instruction Manual users manual for proper catheter connection, defibrillation, pacing and sensing instructions.

ADVERSE EVENTS

Reported Adverse Events

Adverse event rates and device complications are calculated as a percentage of the total number of treatment attempts for each group, namely the internal (study group) and the external (control group). This includes 156 randomized treatments (77 internal and 79 external), 34 crossover treatments (18 internal and 16 external), 3 patients who had an incomplete treatment (3 internal) and 3 patients who were treated twice (2 internal and 1 external).

Each adverse event was assigned a level of severity by the reporting institution. Severity was designated as mild, moderate, severe, and life threatening. Mild – requires no medical intervention moderate – requires mild medical intervention and severe – requires hospitalization. There have been no deaths or unanticipated serious adverse events reported for either the ALERT® System device or the control device.

Adverse events were also stratified according to treatment group and relationship to the device (see Table 1). The manifestations of device-related adverse events from the control and study groups revealed some differences due to the nature of the treatment procedure itself (external vs. internal). The control group received atrial defibrillation therapy from an external device (standard transthoracic cardioversion approach), while the study group received treatment using an internal defibrillation catheter (transvenous procedure).

Forty-seven patients experienced first-degree skin burns, 10 patients developed skin rash, and 2 patients presented with post-procedure chest pain. One patient presented with a slow junctional rhythm after the procedure and was treated with medication. All of them were judged as either mild (50 reports) or moderate (10 reports).

Table 1. Adverse Events Reported for ALERT Study

Device Related Event	External Device Related (n = 96)	ALERT® System Related (n = 100)
Abnormal Rhythm	1 (1%)	2 (2%)
Bleeding/Hematoma	0	3 (3%)
Bruising	0	4 (4%)
Ecchymosis of Catheter Site	0	1 (1%)
Hypotension	0	1(1%)
Infection/sepsis	0	1 (1%)
Pain, post-procedural	2 (2%)	0
Skin Burns	47 (49%)	0
Skin Rash	10 (10%)	0
Soreness at insertion site	0	1 (1%)
Ventricular Tachycardia	0	1 (1%)
Ventricular Fibrillation	0	1 (1%)
Other – hardening of the skin	0	1 (1%)
Other – swelling at insertion site	0	1 (1%)
Total	**60 (62%)**	**17 (17%)**

There were fewer patients who had adverse events related to internal cardioversion using the ALERT® Catheter and ALERT® Companion system. The types of device-related adverse events included ventricular fibrillation, ventricular tachycardia, abnormal rhythms, hypotension (due to a vagal response from the neck stick), infection/sepsis (near the left brachial vein), bruising, hematoma, swelling, soreness, ecchymosis and hardening of the skin, all which occurred at the site of catheter insertion.

The two patients who had abnormal rhythms following the procedure included one with a right bundle branch block that spontaneously resolved and the other with first degree AV block. Neither patient required intervention. In addition to the abnormal rhythms, the two patients undergoing internal cardioversion in which one patient presented with ventricular fibrillation, VF (life threatening) and the other patient presented with ventricular tachycardia, VT (severe) were caused by a malfunction of the ALERT Companion during the ventricular threshold test. The level of severity for the internal treatment group were reported as life-threatening (1) severe (1), moderate (2), mild (13).

Two additional patients undergoing internal cardioversion experienced severe episodes of ventricular tachycardia several days after the internal procedure, both were judged unrelated to the treatment device.

Potential Adverse Events
Potential risks associated with either internal or external cardioversion listed alphabetically:

- ☐ Death
- ☐ Elevation of cardiac enzymes
- ☐ Hypotension
- ☐ Myocardial infarction
- ☐ Other abnormal rhythm (other than atrial fibrillation)
- ☐ Stroke
- ☐ Thromboembolism
- ☐ Ventricular fibrillation
- ☐ Ventricular Tachycardia

Potential risks uniquely associated with external cardioversion include and are listed alphabetically:

- ☐ Joint injury
- ☐ Post-procedural pain
- ☐ Residual muscular weakness or weakness
- ☐ Risks associated with general anesthesia
- ☐ Skin burns
- ☐ Skin rash

The potential risks associated with use of the ALERT Catheter include those encountered with the introduction and placement of any temporary cardiac balloon catheter/pacing lead. Additional risks may be incurred as a result of the delivery of electrical energy during internal defibrillation and are listed alphabetically.

- ☐ Allergic reaction to latex balloon
- ☐ Balloon rupture resulting in air/latex embolus
- ☐ Bleeding, hematoma or thrombus at the catheter introduction site
- ☐ Bruising swelling, and/or irritation at the catheter introduction site
- ☐ Electrode displacement resulting in inappropriate or loss of sensing
- ☐ Electrode displacement resulting in loss of capture
- ☐ Infection/sepsis
- ☐ Intercostal or phrenic nerve stimulation
- ☐ Mechanical induction of arrhythmias or asystole
- ☐ Perforation causing cardiac tamponade with need for percutaneous or surgical drainage

- Perforation of the chamber or vessel wall
- Pneumothorax
- Pulmonary artery rupture or pulmonary hemorrhage
- Pulmonary infarction
- Tricuspid and/or pulmonic valve injury
- Vasospasm

The risks associated with use of the ALERT Companion include those encountered with interfacing any electrical energy source via connecting cables to an intravascular catheter placed in direct contact with the heart. Additional risks may be incurred as a result of the delivery of electrical energy during internal atrial defibrillation.

- Inappropriate sensing of the R-wave resulting in the delivery of a mistimed electrical shock and the subsequent induction of VT or VF
- Loss of electrical output resulting in failure to pace/defibrillate
- Inappropriate electrical output resulting in induction of VT or VF
- Random aberrant behavior resulting in output settings different than those which are displayed or programmed

CLINICAL STUDY

A non-blinded randomized prospective clinical study, in which 156 patients from 12 investigational centers were treated, was performed to determine the safety and effectiveness of the ALERT® System. Patient characteristics for each treatment group are presented in Table 2 below. Internal defibrillation of AF using the ALERT® System was compared to the control intervention of external defibrillation using patches in an A/P orientation. Patients who did not have their AF terminated by the randomized treatment modality were treated with the alternate therapy (i.e., patients randomized to external were treated with internal and patients randomized to internal were treated with external).

Table 2. Characteristic of Patients with AF Undergoing Internal and External Cardioversion (n = 156)

Characteristic	External n (%) mean ± SD	Internal n (%) mean ± SD	Significance
Number of patients	79	77	NS
Age	61 ± 12	61 ± 11	NS
Male (Female)	57 (22)	55 (22)	NS
Body Mass Index	34 ± 9	33 ± 11	NS
BMI => 25	67 (85%)	63 (82%)	NS
Left Atrial Size (mm)	45 ± 6.6	46 ± 5.7	NS
LAD>4.5 cm	43 (54%)	40 (52%)	NS
Left Ventricular Ejection Fraction	47 ± 13	51 ± 12	NS
LVEF<40%	21 (27%)	13 (17%)	NS
Concomitant Heart Disease	47 (59%)	49 (64%)	NS
Failed Prior External Cardioversion	49 (62%)	50 (65%)	NS
Failed Prior Drug Therapy	69 (87%)	62 (81%)	NS
Cardiac Surgery	12 (15%)	11 (14%)	NS
Pacemaker/ICD	4 (5%)	5 (6%)	NS
Duration of AF (months)	8.7 ± 13	8.5 ± 16	NS
Duration AF > 6 months	24 (30%)	22 (29%)	NS

The primary objective of the clinical study was to determine whether the probability of successful termination of atrial fibrillation with the ALERT® System is equivalent to that of external cardioversion. The study endpoint for device effectiveness was the proportion of randomized patient who had their AF terminated by the intervention strategy.

Primary external defibrillation was performed in 79 patients using patch electrodes in an A/P orientation and primary internal defibrillation was performed in 77 patients using the ALERT® System. In addition, internal defibrillation was performed as a crossover procedure in 18 patients who failed to convert with external defibrillation. These patients are listed in the table below in the Combined sections. External defibrillation was performed as a crossover procedure in 16 patients who failed to convert with internal defibrillation. In total, 95 patients underwent internal defibrillation and 95 patients underwent external defibrillation including randomized and crossover procedures.

The combined categories are patients that began the study as external and crossed over to internal, or vice-versa. The primary (conversion to normal sinus rhythm within 5 seconds of the shock) success rate for the internal defibrillation procedure (randomized and crossover treatments combined) is 76% (72 patients successfully converted out of 95) compared with a success rate of 67% for the external defibrillation procedures (64 patients successfully converted out of 95). Primary success rates by Investigational Site for randomized and crossover treatments are shown in Table 3. After 4 weeks of follow-up, 42 out of 68 (62%) of the patients successfully treated with internal defibrillation were still in sinus rhythm compared to 29 out of 55 (53%) of the patients successfully treated with external defibrillation.

Table 3. Proportion of Success for Randomized and Combined Treatments

Treatment	Primary Success Rate (5 Seconds)		Difference	95% C.I.	95% C.I. on Success Rate	
Randomized (n = 156)	Internal	79% (61/77)	4%	-10% to 21%	Internal	68% to 88%
	External	75% (59/79)			External	64% to 84%
Combined (n = 190)	Internal	76% (72/95)	9%	-6% to 23%	Internal	66% to 84%
	External	67% (64/95)			External	57% to 77%
	4-Week Success Rate (4 Weeks)			95% C.I.	95% C.I. on Success Rate	
Randomized (n = 156)	Internal	61% (35/57)	13%	-6% to 34%	Internal	48% to 74%
	External	48% (24/50)			External	34% to 62%
Combined (n = 190)	Internal	62% (42/68)	9%	-6% to 24%	Internal	49% to 73%
	External	53% (29/55)			External	44% to 62%

Table 4 below describes the primary success rates by investigational site for randomized (n = 156) and crossover treatments combined (n = 190). The influence of investigational site interaction on primary success is calculated separately for each treatment group. Both randomized and crossover procedures were combined (n = 190) for the test. The proportion of successful outcomes for each site is listed separately for each treatment group. The probability value for site interaction is provided via the chi-square and the CMH test statistic for each treatment group. The majority of sites reported a success rate of 70% or higher for each of the treatment groups however; 3 sites reported success rates below 50% which results in a chi-square and CMH probability value < 0.05.

Site	Internal Success % (n)	External Success % (n)
Chi-Square	0.003	0.03
CMH	0.003	0.03
01	70% (7/10)	50% (5/10)
02	100% (11/11)	86% (6/7)
03	86% (6/7)	50% (3/6)
04	95% (20/21)	79% (15/19)
05	40% (4/10)	20% (2/10)
06	25% (1/4)	60% (3/5)
07	75% (3/4)	80% (4/5)
09	0% (0/2)	33% (1/3)
10	75% (9/12)	88% (15/17)
11	100% (3/3)	100% (3/3)
12	71% (5/7)	71% (5/7)
13	75% (3/4)	67% (2/3)
Total	76% (72/95)	67% (64/95)

Table 4: **Primary Success Rates by Investigational Site**

During the clinical trial, 17% of the patients treated with the ALERT System experienced mild or moderate treatment related adverse events. This excludes 2 device malfunctions with the ALERT Companion system, which resulted in 1 case of severe ventricular tachycardia and 1 case of life threatening ventricular fibrillation. Conversely 62% of patients treated with external cardioversion experienced mild or moderate treatment related adverse events, most of which were skin burns or skin rashes associated with external defibrillation.

PRODUCT DISCLAIMER OF WARRANTIES

Although due care has been exercised in the design, manufacture and testing of **ALERT®** Catheters and the accessories used therewith, catheters may be damaged before, during and after insertion into the patient by improper storage, handling, cleaning or sterilization. In addition, the diagnosis, surgical procedures and other matters relating to the patient and the treatment of a patient may adversely affect the condition and/ or performance of the catheter. Therefore, no representation or warranty is made that a failure of the catheter will not occur or that a patient will not have an adverse reaction to the introduction of the catheter into the body or that medical complications will not result from the use of the catheter. The catheter and accessories used therewith are sold "as is." EP MedSystems, Inc. disclaims all warranties, expressed or implied, with respect to the catheter and accessories including, but not limited to, any implied warranty of merchantability or fitness for a particular purpose. EP MedSystems, Inc. shall not be liable to any person for any expenses or direct or consequential damages directly or indirectly arising from the use of the catheter whether a claim for such damages is based upon warranty, contract, tort or otherwise EP MedSystems, Inc. neither assumes nor authorizes any other person to assume for it any other additional liability or responsibility with respect to the catheter and accessories used therewith.

PATENTS AND TRADEMARKS

- **ALERT®** is a registered trademark of EPMedSystems.
- **Companion™** is a trademark of EP MedSystems, Inc.
- Teflon® is a registered trademark of Dupont, Inc.
- The **ALERT®** System and/or components are covered by one or more of the following U.S. Patents: No. 5,653,734, No. 5,571,159, No. 5,697,965, No. 6,144,870, No. 5,928,269, No. 5,974,339, No. 6,181,967, No. 5,207,219, No. 5,807,324. Other patents applied for.

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